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10/824,933

04/15/2004

James R. Braig

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EXAMINER

AKANBI, ISIKA O

ART UNIT

PAPER NUMBER

2877

DATE MAILED: 07/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/824,933

Applicant(s)

BRAIG ET AL.

Examiner

Isiaka O. Akanbi

Art Unit

2877

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 15 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-40 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>4 October 2004</u> .  | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Information Disclosure Statement***

The information disclosure statement file 15 July 2004 and 4 October 2004 has been entered and reference considered by the examiner.

### ***Drawings***

The examiner approves the drawings filed 15 April 2004.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wong et al. (6,312,888 B1)

Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wong. The reference of Wong teaches of the features of claim 1, comprising first and second (12/16) substantially parallel faces separated by an intermediate member (14), the parallel faces and the intermediate member at least partially defining a sample chamber configured to hold a volume of fluid (col. 3, line 1-13), an identifying compound disposed within or on at least one of the parallel faces, an optical path extending through the parallel faces and the intermediate member, such that electromagnetic radiation can propagate through the sample chamber (col. 3, line 30-40), the identifying compound (i.e. colorant) having at least one indexed optical absorbance feature, such that spectral analysis of electromagnetic radiation propagated through the sample chamber yields the indexed optical absorbance feature (col. 3, line 17-27), with regard to the following phrase "wherein detection of the indexed optical absorbance feature in

electromagnetic radiation propagated through the sample chamber indicates to an analyte detection system whether the sample element is configured for use with the analyte detection system" it has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

As to claim 2, Wong discloses everything claimed, as applied to claim 1 above, in addition Wong wherein the first and second substantially parallel faces are at least partially transmissive to electromagnetic radiation (col. 15, line 9-21).

As to claims 3 and 4, Wong discloses the claimed invention, as applied to claim 1 above, in addition Wong wherein the parallel faces are at least partially transmissive to infrared electromagnetic radiation and wherein the indexed optical absorbance feature is adjacent to or overlapping an absorbance feature of an analyte detectable by the analyte detection system (col. 9, line 65-col. 10, line 1-39).

As to claim 5, Wong discloses the claimed invention, as applied to claim 1 above, in addition Wong wherein the analyte detectable by the analyte detection system is glucose (col. 1, line 10-11).

As to claim 6, Wong discloses the claimed invention, as applied to claim 1 above, in addition Wong wherein the indexed optical absorbance feature is an absorbance maximum or an absorbance minimum (i.e. appropriate level)(col. 1, line 25-41).

As to claim 7, Wong discloses the claimed invention, as applied to claim 1 above, in addition Wong wherein the identifying compound is a hydrocarbon (i.e. a dye or pigment)(col. 9, line 66-67).

As to claim 8, Wong discloses the claimed invention, as applied to claim 1 above, in addition Wong wherein the identifying compound is a coating on at least a portion of the sample element (col. 3, line 34-37).

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 9-12 and 34-37 are rejected under 35 U.S.C. 102(b) as being anticipated by Jina et al. (5,526,120).

As regard to claims 9, 31-33 and 40, Jina discloses a method for determining an analyte concentration in a material sample element comprising of the following:

an optical path (fig. 2)(col. 1, line 7-11), an identification key (56/60) configured to indicate a physical property of the sample element in the optical path (figs. 1, 4 and 5)(col. 6, line 40-43), inserting the material sample into a sample element, inserting the sample element into an analyte detection system, qualifying the sample element to determine whether the sample element is compatible with the analyte detection system and analyzing an optical property of the material sample (figs. 1, 4-12)(col. 6, line 40-43)(col. 12, line 12-col. 14, line 1-5).

As to claim 10, according to claim 9, Jina discloses wherein the physical property is an optical absorption of a window in the optical path (figs. 1 and 5-12).

As to claims 11 and 12, Jina discloses wherein the physical property is a thickness of a window in the optical path and wherein the physical property is a thickness of a sample chamber in the optical path (figs. 7-12).

As to claim 34, Jina discloses wherein qualifying the sample element comprising measuring an optical absorbance spectrum of the sample element and analyzing the measured optical absorbance spectrum for a qualifying absorbance feature (col. 1, line 6-11).

As to claim 35, Jina discloses wherein the qualifying absorbance feature is an absorbance maximum or an absorbance minimum (col. 3, 38-col. 4, line 1-2).

As to claim 36, Jina discloses wherein qualifying the sample element comprises reading at least one datum from an identification medium (col. 4, line 48-54).

As to claim 37, Jina discloses wherein qualifying the sample element further comprising checking whether the datum corresponds to a datum stored in the analyte detection system (col. 3, line 39-47).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 13 and 38-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jina et al. (5,526,120) in view of Douglas et al. (5,962,215).

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over of Jina in view of Douglas, as applied to claim 9 above. The reference of Jina teaches of the features of claim 13, comprising physical property (figs. 1 and 5-12), however the reference of Jina is silent regarding the wherein the physical property is a background optical absorbance spectrum of the optical path. The reference of Douglas teaches of calibration (col. 6, line 45-53)(col. 16, line 7-15). It would have been obvious to one having ordinary skill in the art at the time of invention to include physical property that is a background optical absorbance spectrum of the optical path for the purpose of providing a more accurate measurement.

As to claims 38 and 39, Jina discloses everything claimed, as applied to claim 36 above, except for the reference of Jina is silent regarding wherein the identification medium comprises a bar code and wherein the identification medium comprises a magnetic strip. The reference of Douglas teaches of a bar code and magnetic strip (col. 24, 43-48). It would have been obvious to one having ordinary skill in the art at the time of invention to provide an identification medium comprising a bar code and a magnetic strip for the purpose of providing a more accurate calibration information and detection.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 14-18 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Douglas et al. (5,962,215).

As regard to claim 14, Douglas discloses a sample element for use with an analyte detection system comprising of the following:

a sample chamber (49) and an identification key (61/101) that is located within or on the sample element and that is configured to indicate to the analyte detection system a qualification state of the sample element (figs. 1-3)(col. 16, line 2-15).

As to claim 15, according to claim 14, Douglas discloses wherein the identification key is configured to indicate a qualification state in which the sample element is configured for use with the analyte detection system (col. 16, line 7-15).

As to claims 16 and 17, Douglas discloses wherein the identification key (61/101) comprising a compound (Barcode on strip) having an optical absorbance spectrum with a qualifying optical absorbance feature and wherein the qualifying optical absorbance feature is adjacent to or overlapping an absorbance feature of an analyte detectable by the analyte detection system (72)(figs. 1-3)(col. 24, line 36-47).

As to claim 18, Douglas discloses wherein the analyte detectable by the analyte detection system is glucose (col. 1, line 13-14).

As to claim 21, Douglas discloses wherein the identification key (61/101) has a structure configured to mechanically engage a complimentary structure in the analyte detection system, such that mechanical engagement of the sample element with the analyte detection system indicates to the analyte detection system a qualification state of the sample element in which the sample element is configured for use with the analyte detection system (fig. 3B)(col. 16, line 6-15).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 19-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Douglas et al. (5,962,215) in view of Wong et al. (6,312,888 B1)

Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over of Douglas in view of Wong, as applied to claims 16. The reference of Douglas teaches of the features of claim 19, comprising qualifying optical absorbance feature (61/101), however the reference of Douglas is silent regarding the qualifying optical absorbance feature as having (i.e. an absorbance maximum or an absorbance minimum). The reference of Wong teaches of optical absorbance feature with (colorant)(i.e. appropriate level)(col. 3, line 17-27) (col. 1, line 25-41). It would have been obvious to one having ordinary skill in the art at the time of invention to provide the qualifying optical absorbance feature that have (i.e. an absorbance maximum or an absorbance minimum) for the purpose of providing a more accurate measurement.

As to claims 20 and 24, Douglas and Wong disclose everything claimed, as applied to claim 19 above, except for the reference of Douglas is silent regarding wherein the compound comprising a hydrocarbon. The reference of Wong teaches of hydrocarbon (i.e. a dye or pigment)(col. 9, line 66-67). It would have been obvious to one having ordinary skill in the art at the time of invention to provide compound that comprises a hydrocarbon (i.e. a dye or pigment) for the purpose of providing a more accurate measurement and detection.

As to claims 25 and 26, Douglas and Wong disclose everything claimed, as applied to claim 24 above, in addition Douglas discloses wherein the identification medium comprising a bar code and magnetic strip (col. 24, 43-48)

Claims 22, 23 and 27-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Douglas et al. (5,962,215) in view of Wong et al. (6,312,888 B1) and further in view of Jina et al. (5,526,120)

Claims 22, 23 and 27-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over of Douglas in view of Wong, and further in view of Jina, as applied to claims 14. The reference of Douglas teaches of the features of claim 21, comprising an identification key (61/101)(fig. 3B)(col. 16, line 6-7), however the reference of Douglas and Wong is silent regarding wherein the identification key structure is a physical shape. The reference of Jina teaches of an identification key (56/60) structure with a physical shape (figs. 1, 4-12)(col. 6, line



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40-43)(col. 12, line12-col. 14. line 1-5). It would have been obvious to one having ordinary skill in the art at the time of invention to provide identification key structure that has a physical shape for the purpose of providing a more accurate calibration and detection

### **Additional Prior Art**

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The references listed in the attached form PTO-892 teach of other prior art sample element that may anticipate or obviate the claims of the applicant's invention.

### **Conclusion**

### **Fax/Telephone Information**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isiaka Akanbi whose telephone number is (571) 272-8658. The examiner can normally be reached on 8:00 a.m. - 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gregory J. Toatley Jr. can be reached on (571) 272-2059. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Isiaka Akanbi  
June 30, 2006



**HWA (ANDREW) LEE**  
**PRIMARY EXAMINER**